

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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S/N 10/698,026

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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|---------------|---|-------------------|------------|
| Appellants: | Jeffrey A. Hall et al. | Examiner: | Alex Toy |
| Serial No.: | 10/698,026 | Group Art Unit: | 3739 |
| Filed: | October 30, 2003 | Docket No.: | 279.401US1 |
| Customer No.: | 45458 | Confirmation No.: | 7128 |
| Title: | ENERGY DELIVERY OPTIMIZATION FOR RF DUTY CYCLE FOR LESION CREATION | | |

APPEAL BRIEF UNDER 37 CFR § 41.37

Mail Stop Appeal Brief- Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

The Appeal Brief is presented in support of the Notice of Appeal to the Board of Patent Appeals and Interferences, filed on August 10, 2009, from the Final Rejection of claims 16-22 of the above-identified application, as set forth in the Office Action mailed on February 9, 2009.

The Commissioner of Patents and Trademarks is hereby authorized to charge Deposit Account No. 19-0743 in the amount of \$540.00 which represents the requisite fee set forth in 37 C.F.R. § 41.20(b)(2). The Appellants respectfully request consideration and reversal of the Examiner's rejections of the pending claims.

1. REAL PARTY IN INTEREST

The real party in interest of the above-captioned patent application is the assignee, Cardiac Pacemakers, Inc., as evidenced by the Assignment recorded on May 3, 2004, at Reel 015285, Frames 0616-0619.

2. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellants that will have a bearing on the Board's decision in the present appeal.

3. STATUS OF THE CLAIMS

The present application was filed on October 30, 2003 with claims 1-28. In response to a Non-Final Office Action mailed on August 8, 2005, Appellants canceled claims 1-15 and 26-28. A Final Office Action was mailed March 31, 2006. In response, Appellants canceled claims 23-25 in a Request for Continued Examination with a response on April 30, 2007. A Non-Final Office Action was mailed on May 9, 2007 and a response was filed on November 8, 2007. A Final Office Action (hereinafter “the Final Office Action”) was mailed on February 9, 2009. Claims 16-22 stand twice rejected, remain pending, and are the subject of the present Appeal.

4. STATUS OF AMENDMENTS

No amendments have been made subsequent to the Final Office Action dated February 9, 2009.

5. SUMMARY OF CLAIMED SUBJECT MATTER

Aspects of the present inventive subject matter include, but are not limited to, Energy Delivery Optimization for RF Duty Cycle for Lesion Creation.

INDEPENDENT CLAIM 16

16. A system for delivering RF energy to an endocardial tissue, the system comprising:
a catheter (110) having one or more electrodes (115) proximate a distal end of the catheter, the catheter configured for being positioned such that the one or more electrodes are adjacent the endocardial tissue (150), at least one of the electrodes including a tip electrode having a thermal time constant of approximately 240 ms; (Figure 1; Page 3, lines 7-11); (Page 7, lines 22-25) and

a power control system (130) configured to provide power to the tip electrode, the power having a plurality of alternating on portions and off portions, one set of adjacent on and off portions defining a duty cycle; (Figure 1; Page 5, lines 14-19)

wherein the power control system delivers an energy pulse of between approximately 0.01 ms to 4 ms via the tip electrode, and the on portions and off portions of the duty cycle have a ratio of between 50% - 100%. (Page 8, lines 23-26).

This summary does not provide an exhaustive or exclusive view of the present subject matter, and Appellants refer to each of the appended claims and its legal equivalents for a complete statement of the invention.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 16, 17, and 19-22 were rejected under 35 USC § 102(b) as anticipated by or, in the alternative, under 35 USC § 103(a) as obvious over Sherman (U.S. Patent No. 6,059,778).

Claim 18 is rejected under 35 USC § 103(a) as being unpatentable over Sherman (*778).

Claim 16-22 are rejected under 35 USC § 103(a) as being unpatentable over Sherman (*778) in view of Sherman (U.S. Patent No. 5,971,980).

7. ARGUMENT

A) The Applicable Law under 35 U.S.C. §102(b)

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. M.P.E.P § 2131. To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter. *PPG Industries, Inc. V. Guardian Industries Corp.*, 75 F.3d 1558, 37 USPQ2d 1618 (Fed. Cir. 1996). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

B) The Applicable Law under 35 U.S.C. §103

The Examiner has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). To do that the Examiner must show that some objective teaching in the prior art or some knowledge generally available to one of ordinary skill in the art would lead an individual to combine the relevant teaching of the references. *Id.*

The Fine court stated that:

Obviousness is tested by “what the combined teaching of the references would have suggested to those of ordinary skill in the art.” *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 878 (CCPA 1981)). But it “cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination.” *ACS Hosp. Sys.*, 732 F.2d at 1577, 221 USPQ at 933. And “teachings of references can be combined only if there is some suggestion or incentive to do so.” *Id.*

The M.P.E.P. adopts this line of reasoning, stating that

In order for the Examiner to establish a *prima facie* case of obviousness, three base criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify

the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Appellant's disclosure. M.P.E.P. § 2142 (citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed.Cir. 1991)).

Moreover, if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984); MPEP § 2143.01.

C) Discussion of the rejection of claims 16, 17 and 19-22 which were rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Sherman (U.S. Patent No. 6,059,778).

Appellant believes that claim 16 is not anticipated or obvious in view of the cited reference since the reference does not include or suggest each limitation recited in the claim. For instance, Appellant cannot find in the cited reference: a tip electrode having a thermal time constant of approximately 240 ms; and a power control system configured to provide power to the tip electrode; and wherein the power control system delivers an energy pulse of between approximately 0.01 ms to 4 ms via the tip electrode, and the on portions and off portions of the duty cycle have a ratio of between 50% - 100%, as recited in claim 16.

In contrast, the cited reference discusses controlling the duty cycle of energy delivered via ring electrodes 32. (Col. 6, lines 8-53). There is no discussion of any details of tip electrode 36. The Office Action asserts that such subject matter is inherent in the cited reference. However, the cited reference includes no discussion of such a capability.

Appellant believes the Office Action has not established a *prima facie* case of inherency because, as recited in MPEP § 2112, "In relying upon the theory of inherency, the examiner must provide basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art,"

citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). Here, the Office Action only argued that Sherman is “inherently capable of this intended use.” (Page 2 of Final Office Action). In the Response to Arguments section of the Final Office Action, the Examiner “maintains that these electrodes would intuitively and inherently be used in the same manner.” (Page 6, Final Office Action). Thus, the Office Action does not even assert that the allegedly inherent characteristic is necessary, let alone provide a basis in fact and/or technical reasoning.

Appellant notes that the Sherman reference does not show or discuss that tip electrode 36 is connected to the power control system in any of the examples or figures of the reference. Thus, the subject matter is not inherent since the Examiner has not provided basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.

Claims 17 and 19-22 include each limitation of their parent claim and are therefore also not anticipated or obvious in view of the cited reference. Reconsideration and allowance is respectfully requested.

D) Discussion of the rejection of claim 18 which was rejected under 35 U.S.C. § 103(a) as being unpatentable over Sherman (U.S. Patent No. 6,059,778).

Claim 18 includes each limitation of its parent claim and is not obvious over the cited reference for the reasons given above. Reconsideration and allowance are respectfully requested.

E) Discussion of the rejection of claims 16-22 which were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sherman (U.S. Patent No. 6,059,778) in view of Sherman (U.S. Patent No. 5,971,980).

Appellant believes claims 16-22 are not obvious over the cited references for the reasons given above. Here, the secondary reference also does not include or suggest: a tip electrode having a thermal time constant of approximately 240 ms; and a power control system configured to provide power to the tip electrode, the power having a plurality of alternating on portions and off portions, one set of adjacent on and off portions defining a duty cycle; wherein the power control system delivers an energy pulse of between approximately 0.01 ms to 4 ms via the tip

electrode, and the on portions and off portions of the duty cycle have a ratio of between 50% - 100%, as recited in claim 16. Reconsideration and allowance is respectfully requested.

SUMMARY

For the reasons argued above, claims 16-22 were not properly rejected under §102/ §103.


It is respectfully submitted that the art cited does not render the claim anticipated or obvious and that the claims are patentable over the cited art. Reversal of the rejection and allowance of the pending claim are respectfully requested.

Respectfully submitted,

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By

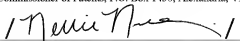


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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Appeal Brief— Patents, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 10th day of March, 2010.

Nellie Nuhring

Name


Signature

8. CLAIMS APPENDIX

16. A system for delivering RF energy to an endocardial tissue, the system comprising:
a catheter having one or more electrodes proximate a distal end of the catheter, the catheter configured for being positioned such that the one or more electrodes are adjacent the endocardial tissue, at least one of the electrodes including a tip electrode having a thermal time constant of approximately 240 ms; and
a power control system configured to provide power to the tip electrode, the power having a plurality of alternating on portions and off portions, one set of adjacent on and off portions defining a duty cycle;
wherein the power control system delivers an energy pulse of between approximately 0.01 ms to 4 ms via the tip electrode, and the on portions and off portions of the duty cycle have a ratio of between 50% - 100%.
17. The system of claim 16, wherein the duty cycle chosen ranges from 80% to 100%.
18. The system of claim 16, wherein the tip electrode includes an approximately 5 mm tip with a diameter of approximately .094 inches.
19. The system of claim 16, wherein the RF energy has a period of between 120 ms and 240 ms.
20. The system of claim 16, wherein the RF energy has a period of greater than 240 ms.
21. The system of claim 16, wherein the power control system delivers the energy pulse having an effective peak power of 150 W.
22. The system of claim 16, wherein one of the one or more electrodes includes a ring electrode.

9. EVIDENCE APPENDIX

None.

10. RELATED PROCEEDINGS APPENDIX

None.